



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of David McElroy *et al.*

Appln. No. 09/801,261

Filed: March 7, 2001

For: Homologous Recombination-Mediated  
Transgene Alteration in Plants

Art Unit : 1638

Examiner : David Fox

Atty. Docket: DEKM:186US

**APPELLANT'S BRIEF**

Mail Stop Appeal Brief-Patents  
Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Sir:

This is an appeal of the final rejection of claims 52-65 pending in the above-described patent application. A Notice of Appeal was received by the USPTO via Facsimile Transmission on September 23, 2002. This Brief is timely submitted in triplicate.

Submitted herewith is a Fee Transmittal for FY2004 authorizing the Commissioner to charge the statutory fee of \$330 for submitting this Brief to deposit account number 314125.

**1. Real Party in Interest** This application is assigned to DeKalb Genetics Corporation, which is a wholly-owned subsidiary of Monsanto Company, a Delaware corporation with offices at 800 North Lindbergh Boulevard, St. Louis, Missouri 63167. The real party in interest is Monsanto Company.

**2. Related Appeals and Interferences** Appellant is unaware of any other Appeals or Interferences related to this Appeal.

**3. Status of Claims** Originally filed claims 1-51 are cancelled and pending claims 52-65 stand rejected under the judicially created doctrine of provisional obviousness-type double patenting as

**Certificate of Mailing under 37 CFR 1.8**

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as first class mail in an envelope addressed Mail Stop Appeal Brief-Patents, Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450 on **November 17, 2003.**

Pamela C. Ball  
Pamela C. Ball, Reg. No. 53,963

11/17/03  
Date

09801261

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being unpatentable over claims of U.S. Patent No. 6,580,019 which issued from parent application Serial No. 09/521,557. The issued claims are listed in Appendix A.

Of the rejected claims on appeal, claim 52 is independent, claims 53, 56, 58, and 60-65 are dependent from claim 52, claims 54 and 55 are dependent from claim 53, claim 57 is dependent from claim 56 and claim 59 is dependent from claim 58. The rejected claims are listed in Appendix B. The outstanding rejection of pending claims 52-65 is appealed.

**4. Status of Amendments** The Advisory Action mailed July 7, 2003 stated that upon the filing of an appeal, the amendment to claims 52 and 53 proposed in the communication filed June 17, 2003 will be entered. The amendment is included in the appended claims.

**5. Summary of Invention** In the method of the present invention, non-reciprocal homologous recombination is used to remove all marker gene sequences situated between two related DNA sequences, resulting in the production of a marker-free transgenic plant.

This invention, as more specifically stated in independent claim 52, provides a method of preparing a marker-free fertile transgenic plant having all marker gene sequences removed from transgene insertions which comprise at least one marker gene DNA sequence flanked by directly repeated DNA sequences which are not recognized by a site-specific recombinase enzyme. Following homologous recombination, e.g. during the natural reproduction of progeny plants, certain progeny plants are marker-free and lack all marker gene sequences. The method comprises selecting a progeny fertile transgenic plant having all marker gene sequences deleted.

The marker genes removed by the method of the invention may be selectable marker genes or reporter genes (claim 53), for example *NPTII*, *bar* or *EPSPS* marker genes (claim 54) or *uidA*, *gfp* or *R*-locus reporter genes (claim 55).

The method may be practiced on any type of transgenic monocot or dicot plant (claims 56 and 58); preferred crop plants are specified in claims 57 and 59. The method is especially useful for producing marker-free, fertile transgenic maize and the marker-free transgene is heritable from generation to generation by self-fertilization, outcrossing or inbreeding (claims 60-62). One practicing the invention is able to delete marker genes from homozygous transgenic plants at a frequency of at least 0.1%, up to a frequency of at least 2%. Thus, without the use of site specific recombinases, integrases or specific site-specific recombination sites, one is able to

utilize the DNA recombination mechanisms resident in the plant cell to delete all marker sequences flanked by directly repeated DNA sequences in a transgenic insert in a plant.

**6. Issues** The sole issue in this appeal is whether independent claim 52 and dependent claims 53-65 are unpatentable under the judicially created doctrine of obviousness-type double patenting over claims of U.S. Patent No. 6,580,019 which issued from parent application Serial No. 09/521,557. Those claims are set forth in Appendix A.

The issued claims are directed to a method of preparing a fertile transgenic cereal plant having an altered transgene insertion. The method comprises obtaining a first fertile transgenic cereal plant homozygous for a transgene insertion DNA sequence. The transgene insertion DNA sequence comprises a pre-selected DNA sequence flanked by directly repeated DNA sequences. The directly repeated sequences are not recognized by a site-specific recombinase enzyme. The method comprises selecting a progeny fertile transgenic cereal plant wherein at least a portion of the transgene insertion is altered (i.e., deleted, amplified or rearranged) as compared to the first fertile transgenic cereal plant.

**7. Grouping of claims** As all rejected claims are directed to a method of preparing marker-free, fertile transgenic plants, Appellant consents to the Board deciding the merits of this appeal with consideration only of the broadest claim on appeal, i.e. claim 52.

## **8. Argument**

### **Obviousness-Type Double Patenting Rejection**

Pending claims 52-65 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims in U.S. Patent No. 6,580,019. In the Advisory Action, the Examiner maintains that the instant claims are co-extensive with the claims issued from the parent application and states that there is “no evidence of non-obviousness (i.e., unexpected results) to extrapolate monocot method of the parent to other agronomic crops as claimed in claim 52, particularly when dependent claims of instant are limited to monocots/cereals.”

Appellants argue however, that it is not obvious to apply the monocot method of the parent application to non-crop or dicot plants for the removal of all marker gene sequences.

Applicants submit that amendment to claim 52, requiring removal of all marker genes, renders the rejected claims even more patentably distinct from the issued claims which do not require or suggest removal of all marker gene sequences. Issued claims from U.S. Patent No. 6,580,019 are directed to the alteration of at least a portion of the transgene in a monocot plant such that the portion is deleted, amplified or rearranged. The claims do not require the complete removal of marker sequences. The Examiner has provided no motivation of evidence to a person of ordinary skill in the art to modify the method of the issued claims to obtain complete removal of marker genes. Rejections for obviousness-type double patenting must be supported by clear evidence. See *In re Kaplan* 229 USPQ 678 (Fed. Cir. 1986). Additionally, it is impermissible to use the common disclosure of the inventions as though it were prior art to support an obviousness aspect of the rejection. Absent such motivation and evidence, Appellants maintain that the rejection is improper.

Appellants traverse the Examiner's assertion that the claims of the issued parent application and the pending application are co-extensive. Appellants submit that the claims of the parent patent and the pending application are not only distinct but, in fact, show a two-way distinctness.

The issued claims are directed to a method of preparing a fertile transgenic cereal plant having an altered transgene insertion while the rejected claims are directed to a method of preparing a marker-free, fertile transgenic plant having all marker gene sequences removed from transgene insertions. The rejected claims are distinct, e.g. the rejected claims could be infringed by applying the method to a dicot plant without infringing the issued claims. One-way distinctness is present in that the issued claims could be infringed by deleting one, but not every, marker gene from a transgene insert in a cereal plant without infringing the rejected claims. Alternatively, one-way distinctness is present in that the issued claims could be infringed by amplification or rearrangement of a transgene DNA without infringing the rejected claims. Appellants also point out that according to the method of the issued claims, the alteration of the transgene insertion may involve any DNA sequences flanked by directly repeated DNA sequence and is not limited to the alteration of a marker gene.

Two-way distinctness is present because the method of the rejected claims can be infringed by the deletion of all marker genes from a dicot plant without infringing the issued claims. Clearly, there is two-way distinctness. Appellants maintain that the same invention is

not twice claimed in the two applications (See *In re Vogel* 164 USPQ 619 (CCPA 1970)) and that a marker free plant is not an obvious variation of the issued claims.

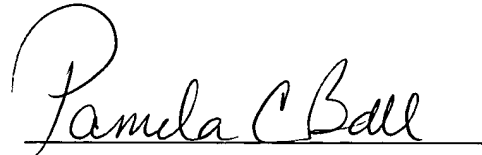
Lacking a motivation to apply the monocot method of the parent to the instant claims, as well as the existence of examples showing two-way distinctness between the claims of the parent and pending applications, Appellant requests reconsideration and withdrawal of the provisional obviousness-type double patenting rejection.

## CONCLUSION

In view of the foregoing, it is respectfully requested that the Board of Patent Appeals and Interferences reverse the final rejection of all of the appealed claims.

Respectfully submitted,

Date: November 17, 2003

A handwritten signature in cursive script, reading "Pamela C. Ball", written over a horizontal line.

Pamela C. Ball

Registration No. 53,963

Agent for Appellant

Phone: 860-572-5265

Appendix A. Issued claims of U.S. Patent No. 6,580,019.

What is claimed is:

1. A method of preparing a fertile transgenic cereal plant having an altered transgene insertion, comprising: a) obtaining a first fertile transgenic cereal plant homozygous for a transgene insertion DNA sequence, wherein the transgene insertion DNA sequence comprises a pre-selected DNA sequence flanked by directly repeated DNA sequences, wherein said directly repeated sequences are not recognized by a site-specific recombinase enzyme; b) obtaining a plurality of progeny of any generation of the first fertile transgenic cereal plant; and c) selecting a progeny fertile transgenic cereal plant wherein at least a portion of the transgene insertion is altered as compared to the first fertile transgenic cereal plant.
2. The method of claim 1 wherein the pre-selected DNA sequence comprises a selectable marker gene or a reporter gene.
3. The method of claim 1 wherein the pre-selected DNA sequence comprises a bar, nptII, or cryIA(b) gene.
4. The method of claim 1 wherein the plurality of progeny plants are obtained by self-pollination.
5. The method of claim 1 wherein the plurality of progeny plants are obtained by outcrossing to produce hybrid progeny.
6. The method of claim 1 wherein the plurality of progeny plants are obtained by inbreeding to produce inbred plants.
7. The method of claim 1 wherein the cereal plant is a maize, barley, wheat, rye or rice plant.
8. The method of claim 7 wherein the plant is a maize plant.
9. The method of claim 1 wherein at least a portion of the transgene insertion is altered in that it has been deleted, amplified, or rearranged.

Appendix B. Listing of pending claims as amended.

What is claimed is:

52. A method of preparing a marker-free fertile transgenic plant having all marker gene sequences removed from transgene insertions comprising:

a) obtaining a first fertile transgenic plant homozygous for a transgene insertion DNA sequence, wherein the transgene insertion DNA sequence comprises at least one marker gene DNA sequence flanked by directly repeated DNA sequences, wherein said directly repeated sequences are not recognized by a site-specific recombinase enzyme;

b) obtaining a plurality of progeny of any generation of the first fertile transgenic plant; and

c) selecting a progeny fertile transgenic plant wherein all marker gene sequences are deleted.

53. The method of claim 52 wherein the marker gene comprises a selectable marker gene or reporter gene.

54. The method of claim 53 wherein the selectable marker gene comprises a *bar*, *nptII*, or a glyphosate resistant EPSPS enzyme gene.

55. The method of claim 53 wherein the reporter gene comprises a *uidA* gene, a *gfp* gene or an R-locus gene.

56. The method of claim 52 wherein the plant is a monocot.

57. The method of claim 56 wherein the monocot plant is a maize, barley, sorghum, wheat, rye or rice plant.

58. The method of claim 52 wherein the plant is a dicot.

59. The method of claim 58 wherein the dicot plant is a soybean, cotton, canola, or potato plant.

60. The method of claim 52 wherein said plant is maize and the plurality of progeny plants are obtained by self pollination.

61. The method of claim 52 wherein said plant is maize and the plurality of progeny plants are obtained by outcrossing to produce hybrid progeny.

62. The method of claim 52 wherein said plant is maize and the plurality of progeny plants are obtained by inbreeding to produce inbred plants.

63. The method of claim 52 wherein the marker gene is deleted at a frequency of at least 0.1%.

64. The method of claim 52 wherein the marker gene is deleted at a frequency of at least 0.6%.

65. The method of claim 52 wherein the marker gene is deleted at a frequency of at least 2%.





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Pamela C. Ball  
Pamela C. Ball, Reg. No. 53,963

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This invention, as more specifically stated in independent claim 52, provides a method of preparing a marker-free fertile transgenic plant having all marker gene sequences removed from transgene insertions which comprise at least one marker gene DNA sequence flanked by directly repeated DNA sequences which are not recognized by a site-specific recombinase enzyme. Following homologous recombination, e.g. during the natural reproduction of progeny plants, certain progeny plants are marker-free and lack all marker gene sequences. The method comprises selecting a progeny fertile transgenic plant having all marker gene sequences deleted.

The marker genes removed by the method of the invention may be selectable marker genes or reporter genes (claim 53), for example *NPTII*, *bar* or *EPSPS* marker genes (claim 54) or *uidA*, *gfp* or *R*-locus reporter genes (claim 55).

The method may be practiced on any type of transgenic monocot or dicot plant (claims 56 and 58); preferred crop plants are specified in claims 57 and 59. The method is especially useful for producing marker-free, fertile transgenic maize and the marker-free transgene is heritable from generation to generation by self-fertilization, outcrossing or inbreeding (claims 60-62). One practicing the invention is able to delete marker genes from homozygous transgenic plants at a frequency of at least 0.1%, up to a frequency of at least 2%. Thus, without the use of site specific recombinases, integrases or specific site-specific recombination sites, one is able to

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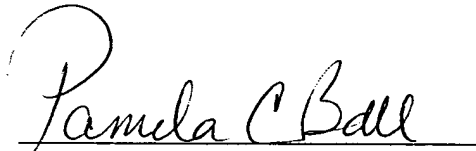
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## CONCLUSION

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Date: November 17, 2003

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Pamela C. Ball

Registration No. 53,963

Agent for Appellant

Phone: 860-572-5265

Appendix A. Issued claims of U.S. Patent No. 6,580,019.

What is claimed is:

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2. The method of claim 1 wherein the pre-selected DNA sequence comprises a selectable marker gene or a reporter gene.
3. The method of claim 1 wherein the pre-selected DNA sequence comprises a bar, nptII, or cryIA(b) gene.
4. The method of claim 1 wherein the plurality of progeny plants are obtained by self-pollination.
5. The method of claim 1 wherein the plurality of progeny plants are obtained by outcrossing to produce hybrid progeny.
6. The method of claim 1 wherein the plurality of progeny plants are obtained by inbreeding to produce inbred plants.
7. The method of claim 1 wherein the cereal plant is a maize, barley, wheat, rye or rice plant.
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53. The method of claim 52 wherein the marker gene comprises a selectable marker gene or reporter gene.

54. The method of claim 53 wherein the selectable marker gene comprises a *bar*, *nptII*, or a glyphosate resistant EPSPS enzyme gene.

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57. The method of claim 56 wherein the monocot plant is a maize, barley, sorghum, wheat, rye or rice plant.

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59. The method of claim 58 wherein the dicot plant is a soybean, cotton, canola, or potato plant.

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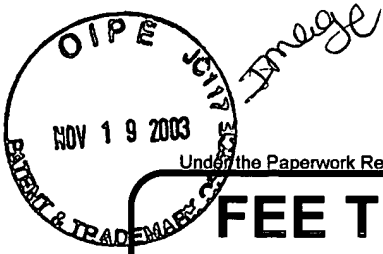
62. The method of claim 52 wherein said plant is maize and the plurality of progeny plants are obtained by inbreeding to produce inbred plants.

63. The method of claim 52 wherein the marker gene is deleted at a frequency of at least 0.1%.

64. The method of claim 52 wherein the marker gene is deleted at a frequency of at least 0.6%.

65. The method of claim 52 wherein the marker gene is deleted at a frequency of at least 2%.





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PTO/SB/17 (10-03)

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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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# FEE TRANSMITTAL for FY 2004

Effective 10/01/2003. Patent fees are subject to annual revision.

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$ 330

## Complete if Known

Application Number	09/801,261
Filing Date	03/07/2001
First Named Inventor	David McElroy et al.
Examiner Name	David T. Fox
Art Unit	1638
Attorney Docket No.	DEKM186US

## METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None

☒ Deposit Account:

Deposit Account Number: 134125  
Deposit Account Name: Monsanto Company

The Director is authorized to: (check all that apply)

☒ Charge fee(s) indicated below ☒ Credit any overpayments

☐ Charge any additional fee(s) or any underpayment of fee(s)

☐ Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.

## FEE CALCULATION

### 1. BASIC FILING FEE

Large Entity	Small Entity	Fee Description	Fee Paid
Fee Code (\$)	Fee Code (\$)		
1001 770	2001 385	Utility filing fee	
1002 340	2002 170	Design filing fee	
1003 530	2003 265	Plant filing fee	
1004 770	2004 385	Reissue filing fee	
1005 160	2005 80	Provisional filing fee	
SUBTOTAL (1)			(\$)

### 2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

Total Claims	Extra Claims	Fee from below	Fee Paid
Independent Claims	-20** =	X	
Multiple Dependent	-3** =	X	

Large Entity	Small Entity	Fee Description
Fee Code (\$)	Fee Code (\$)	
1202 18	2202 9	Claims in excess of 20
1201 86	2201 43	Independent claims in excess of 3
1203 290	2203 145	Multiple dependent claim, if not paid
1204 86	2204 43	** Reissue independent claims over original patent
1205 18	2205 9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) (\$)

\*\*or number previously paid, if greater; For Reissues, see above

## FEE CALCULATION (continued)

### 3. ADDITIONAL FEES

Large Entity	Small Entity	Fee Description	Fee Paid
Fee Code (\$)	Fee Code (\$)		
1051 130	2051 65	Surcharge - late filing fee or oath	
1052 50	2052 25	Surcharge - late provisional filing fee or cover sheet	
1053 130	1053 130	Non-English specification	
1812 2,520	1812 2,520	For filing a request for <i>ex parte</i> reexamination	
1804 920*	1804 920*	Requesting publication of SIR prior to Examiner action	
1805 1,840*	1805 1,840*	Requesting publication of SIR after Examiner action	
1251 110	2251 55	Extension for reply within first month	
1252 420	2252 210	Extension for reply within second month	
1253 950	2253 475	Extension for reply within third month	
1254 1,480	2254 740	Extension for reply within fourth month	
1255 2,010	2255 1,005	Extension for reply within fifth month	
1401 330	2401 165	Notice of Appeal	
1402 330	2402 165	Filing a brief in support of an appeal	330
1403 290	2403 145	Request for oral hearing	
1451 1,510	1451 1,510	Petition to institute a public use proceeding	
1452 110	2452 55	Petition to revive - unavoidable	
1453 1,330	2453 665	Petition to revive - unintentional	
1501 1,330	2501 665	Utility issue fee (or reissue)	
1502 480	2502 240	Design issue fee	
1503 640	2503 320	Plant issue fee	
1460 130	1460 130	Petitions to the Commissioner	
1807 50	1807 50	Processing fee under 37 CFR 1.17(q)	
1806 180	1806 180	Submission of Information Disclosure Stmt	
8021 40	8021 40	Recording each patent assignment per property (times number of properties)	
1809 770	2809 385	Filing a submission after final rejection (37 CFR 1.129(a))	
1810 770	2810 385	For each additional invention to be examined (37 CFR 1.129(b))	
1801 770	2801 385	Request for Continued Examination (RCE)	
1802 900	1802 900	Request for expedited examination of a design application	

Other fee (specify)

\*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$ 330

## SUBMITTED BY

(Complete if applicable)

Name (Print/Type)	Pamela C. Ball	Registration No. (Attorney/Agent)	53,963	Telephone	860-572-5265
Signature	Pamela C. Ball	Date	11/17/03		

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